



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1309, and 1321

[Docket No. DEA-587]

RIN 1117-AB58

Requiring Online Submission of Applications for and Renewals of DEA Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This rulemaking amends the Drug Enforcement Administration's (DEA) regulations to now require all applications for DEA registrations, and renewal of those registrations, to be submitted online.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) has the legal authority to amend its regulations to require online applications pursuant to the Controlled Substances Act (CSA). The CSA grants the Attorney General authority to promulgate rules and regulations relating to: the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals; reporting changes to professional or business addresses; and the efficient execution of his statutory functions. 21 U.S.C. 821, 822(a), 827(h), 871(b),

957(a). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances and listed chemicals. 21 U.S.C. 958(f). The Attorney General has delegated this authority to the Administrator of DEA. 28 CFR 0.100(b).

Need for Regulatory Changes

Regulatory changes are needed to modernize DEA's approach to registration and renewal applications. The proposed changes require online submission and eliminate inefficient paper applications. Typographical errors or missing pieces of information routinely resulted in delayed or rejected applications. DEA has determined the online application process will prove more efficient and effective for both DEA and registrants.

Purpose of the Rule

This rule mitigates issues created by paper applications by simplifying the process by which registrants submit new applications for registration, or renew current registrations. Previously, DEA regulations permitted the aforementioned DEA Registration Forms (224/224a, 225/225a, 363/363a, and 510/510a) to be submitted either through a secure online portal or via delivery to DEA Headquarters.¹ This rule amends DEA regulations by requiring all registration and renewal applications be submitted only through the secure online portal. The Administration believes this rule will mitigate some of the issues associated with paper applications by reducing inefficiencies and facilitating the application process. After careful consideration, DEA has determined that it is not necessary to amend the proposed regulations related to batch processing, because the regulations currently allow, and will continue to allow, the submission of batch applications. This rule is consistent with agency-wide efforts

¹ <https://www.deadiversion.usdoj.gov/drugreg/index.html#regapps>.

to reduce reliance on antiquated paper submissions and to facilitate electronic document processing.²

Summary of Changes

This rule amends DEA regulations by revising current sections to clarify how registrants must apply, by adding new instructions, and by removing obsolete instructions. The rule amends existing DEA regulations in seven sections.³ Title 21 CFR 1301.13 and 1301.14 are amended to remove the option to submit paper forms and provide instructions for online application and payment instructions. This rule also amends § 1301.14 (b), which will become obsolete with the adoption of the secure application portal. Section 1309.12 is amended to specify which payment options DEA will accept now that paper applications are no longer accepted. Section 1309.32 removes the option to submit paper forms and provides instructions for online applications and payments for listed chemical handlers. Section 1309.33 clarifies the online application and payment process while removing paragraph (b), which will become obsolete with the secure application portal. Section 1309.34 is also amended to clarify the handling of defective applications. Section 1321.01 is amended to remove reference to submitting paper forms by mail to any DEA Registration Unit address.

This rule affects DEA Forms relating to applications for registration and renewal of registrations, namely DEA Forms 224, 224a, 225, 225a, 363, 363a, 510, and 510a. DEA Form 224 applies to new registration applications for practitioners, hospitals and clinics, retail pharmacies, online pharmacies, central fill pharmacies, and teaching institutions.⁴

² See *Reporting of Theft or Significant Loss of Controlled Substances*, 85 FR 45547 (July 29, 2020) (published notice of proposed rulemaking proposing to require all DEA Form 106's to be submitted electronically); see *Suspicious Orders of Controlled Substances*, 85 FR 69282 (Nov. 2, 2020) (published notice of proposed rulemaking proposing centralized electronic reporting for Suspicious Orders Report System (SORS) based on Congressional mandate); see *Agency Rule List- Fall 2021* (2021), https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST¤tPub=true&agencyCode=&showStage=active&agencyCd=1100&csrf_token=F19C7C599C70B80C228EC16B60AEB150F6339AF3C80E56FE003EEB7D3A758895BC8E16A215E8A0466326EBFBA8639F799E09 (Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions, Active Regulatory Actions Listed By Agency, Agency Rule list noting proposed rule stage for Electronic Submission of DEA Form 41 (Registrant Record of Controlled Substances Destroyed) -1117-AB59).

³ 21 CFR 1301.13, 1301.14, 1309.12, 1309.32, 1309.33, 1309.34, and 1321.01.

⁴ 21 CFR 1301.13(e)(1)(iv).

DEA Form 225 applies to new registration applications for manufacturers, distributors, researchers, canine handlers, analytical laboratories, importers, and exporters.⁵ DEA Form 363 applies to new registration applications for narcotic treatment programs.⁶ DEA Form 510 applies to new registration applications for all domestic handlers of List I chemicals.⁷ DEA Forms 224a, 225a, 363a, and 510a address registration renewal applications.⁸

Discussion of Comments

Introduction

On January 7, 2021, DEA published a notice of proposed rulemaking (“NPRM”) that proposed requiring that all applications for DEA registrations, and renewal of those registrations, be submitted online. 86 FR 1030 (Jan. 7, 2021). DEA received four comments from the public on this NPRM, three from individuals and one from the National Association of Chain Drug Stores (NACDS). After closely analyzing each comment, DEA is promulgating this rule as proposed in the NPRM with one exception: DEA is clarifying that Automated Clearing House (ACH) fund transfers will be accepted as payment for registrations and renewals.

Comment from National Association of Chain Drug Stores

DEA received a comment from NACDS on March 8, 2021, about problems that may arise once paper applications and payments are no longer accepted. In particular, NACDS expressed concern about ambiguity surrounding whether DEA will accept “batch” renewals, whether the whole batch will be denied if one application is denied, and whether alternative payment options will be accepted. DEA has reviewed these comments and revised § 1309.12(b) to specify that ACH funds transfer will be accepted as a payment option, in addition to credit cards and other forms of payment that may become available.

⁵ 21 CFR 1301.13(e)(1)(i)-(iii), (v)-(vi), and (viii)-(x).

⁶ 21 CFR 1301.13(e)(1)(vii).

⁷ 21 CFR 1309.21.

⁸ 21 CFR 1301.13(e)(1) and 1309.21

First, NACDS observed that DEA neither proposes to modify nor to address “batch” submissions, a process by which companies seek to renew their registrations for multiple locations with a single packet covering a number of DEA registrations and licenses. The packet usually contains a single signed affidavit as well as a single payment. NACDS believes this process allows corporations to manage the licensing and registration process of thousands of sites efficiently. Thus, NACDS expressed its desire that DEA continue to permit registrants to submit batch applications.

NACDS argued, and DEA agrees, that this process streamlines the renewal process for both companies and DEA. Accordingly, DEA’s online portal will accept online batch applications and single payments for batch renewals. After careful consideration, however, DEA has determined that it is not necessary to amend the proposed regulations on this point.

Next, NACDS asserted that, “[c]larity is needed regarding the rejection of an application submitted in a batch submission.” In particular, NACDS argued it is unclear whether individual applications in a batch could be rejected, or whether a single faulty application would cause its entire batch to be rejected. NACDS therefore proposes that DEA create an electronic means for registrants to correct issues with individual applications in a batch, rather than having to resubmit a batch or otherwise inhibit the application process.

Amending DEA regulations is unnecessary, as this comment displays a fundamental misunderstanding of the online application process itself. Step one of this process involves inputting all necessary information and attaching all relevant documents. Step two involves an internal automated verification process through which DEA’s system analyzes all information submitted and determines if an application is complete. Only completed applications actually are processed, including for payment. Since this process ensures that applicants will not be able to submit incomplete applications, NACDS’ concern that entire batches could be rejected based on individual application deficiencies is moot.

Last, NACDS noted that in § 1309.12(b), the only payment option listed is “credit card.” NACDS thus assumed that the only form of payment DEA accepts is a credit card. NACDS noted that this would be troublesome for payments made in batch renewals (which can cost in excess of \$1 million), as strict corporate policies and procedures often demand that large financial transactions be conducted via certified bank check.

DEA understands and appreciates the concerns expressed by NACDS, and has therefore amended § 1309.12(b) to provide that payment shall be made online by Automated Clearing House (ACH) funds transfer, by credit card, or by any other means made available at the time of submission using the secure application portal at www.DEAdiversion.usdoj.gov. DEA recognizes that some companies may be required to alter their payment methods based on this rule change, as bank checks may be the most convenient option for some registrants. DEA believes, however, that the expansion of this rule to permit ACH transfers will mitigate many of the issues typically surrounding the financial, procedural, or security concerns for applicants. On balance, DEA also believes that this regulation change will promote the policy of increasing efficiency while maintaining a convenient payment process. In keeping with its broader policy of reducing reliance on tangible forms of payment, DEA will not accept bank checks for the foreseeable future.

Other Comments

One commenter supported the proposed amendments, stating the rule would be beneficial given the utilization of modern technology to submit documents electronically, as is common among other agencies. Moreover, the commenter noted that processes that were traditionally done via mail, such as fingerprints and verification of payment, can easily be verified and submitted electronically. Last, the commenter noted that the rule would be beneficial given the “current situation and restrictions given in-person interaction.”

Another commenter supported the rule as a “good change for the DEA,” noting that it will prove better for the environment, more efficient, and that “online is the future.” The

commenter does note, however, that there is a privacy concern given the potential for this information to be accessed via hacking. DEA routinely evaluates the security mechanisms of all of its electronic processes, and expends considerable time and resources to protect the privacy of all registrants and applicants.

Last, one citizen requested information as to where to locate DEA Form 225. Given the nature of the rulemaking process, DEA considers this comment to be a mistake, but nevertheless refers the commenter to *www.deadiversion.usdoj.gov* for further information.

DEA has reviewed closely all comments, and decided to promulgate the regulations as written with the exception of permitting ACH funds transfers as a payment option. DEA appreciates the public's participation in the rulemaking process, and encourages the public to continue submitting comments in the future for all proposed rules.

Regulatory Analyses

Executive Orders 12866, 13563, Regulatory Planning and Review, and Improving Regulation and Regulatory Review

This rule was promulgated in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866.

E.O. 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or

communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

This final rule implements all of the changes discussed in the NPRM, and thus imposes no additional costs on registrants. OMB has determined that this final rule is not a “significant regulatory action” under E.O. 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by OMB.

Executive Order 12988, Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens. DEA expects the instant validation of online registration applications to reduce ambiguity and reduce the number of errors in submissions and reduce burdens on both DEA and registrants.

Executive Order 13132, Federalism

This rule does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

The rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on substantial number of small entities. DEA has analyzed the economic impact of each provision of this rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

In accordance with the RFA, DEA reviewed the economic impact of this rule on small entities and evaluated the impact in the NPRM. DEA's economic impact evaluation indicated that the rule proposed in the NPRM would not have a significant economic impact on a substantial number of small entities. This conclusion applies equally to the final rule, which implements all of the changes discussed in the NPRM.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act of 1995 (UMRA),⁹ DEA has determined that this action will not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year." Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act

This rule modifies existing collection(s) of information required under the Paperwork Reduction Act (PRA).¹⁰ Pursuant to the PRA,¹¹ DEA has identified the collections of information below related to this rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number.¹²

⁹ 2 U.S.C. 1501, *et seq.*

¹⁰ 44 U.S.C. 3501–3521.

¹¹ 44 U.S.C. 3507(d).

¹² Copies of existing information collections approved by OMB may be obtained at <https://www.reginfo.gov/public/do/PRAMain>.

DEA is amending its regulations for all new and renewal registration applications to implement the requirement of online submission through the DEA Diversion Control Division website. This amendment will improve the submission process by aligning it with the Administration's current requirements for other online form submissions. The online submission of DEA Forms 224/224a, 225/225a, 363/363a, 510/510a are now filed with DEA through the DEA Diversion Control Division secure network (available on the DEA Diversion Control Division website). The online submission of new and renewal applications will ensure the Administration's receipt of applications in a more timely and organized manner.

DEA solicited comments from the public regarding the following:

- Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information will have practical utility.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

DEA solicited comments on the aforementioned subjects and received no comments. As a result, DEA is finalizing the collection with no changes.

Congressional Review Act

This rulemaking is a "rule" pursuant to the Congressional Review Act, 5 U.S.C. 801 *et seq.*¹³ This rulemaking is not a "major rule" as it does not have an annual effect on the

¹³ 5 U.S.C. 804(3); *see* 5 U.S.C. 551(4).

economy of over 100 million dollars, constitute a major increase in cost for registrants, nor does it have significant adverse effects on the United States domestic or foreign economy.¹⁴ DEA will submit a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1321

Administrative practice and procedure.

For the reasons stated in the preamble, DEA amends 21 CFR parts 1301, 1309, and 1321 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

2. Amend § 1301.13 by revising paragraphs (e)(2) and (3) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

¹⁴ 5 U.S.C. 804(2)(A)-(C).

(2) DEA Forms 224, 225, and 363 may be obtained online at *www.DEAdiversion.usdoj.gov*. Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

(3) DEA will send renewal notifications via email to registrants approximately 60 calendar days prior to their registration expiration date. Registrants are responsible for maintaining a current email address in application portal on DEA's website. DEA Forms 224a, 225a, and 363a may be obtained online at *www.DEAdiversion.usdoj.gov*. Only renewal applications submitted online through the secure application portal on DEA's website will be accepted for processing.

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3. Amend § 1301.14 by:

- a. Revising paragraph (a);
- b. Removing paragraph (b);
- c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c); and
- d. Revising newly redesignated paragraph (b).

The revisions read as follows:

§ 1301.14 Filing of application; acceptance for filing; defective applications.

(a) All applications for registration shall be submitted for filing online using the secure application portal at *www.DEAdiversion.usdoj.gov*.

(b) Application submitted for filing are dated by the system upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will be rejected by the system, with the applicant receiving error messages at the time of application.

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**PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS,
IMPORTERS AND EXPORTERS OF LIST I CHEMICALS**

4. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

5. Revise § 1309.12 to read as follows:

§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture, distribute, import, or export the applicant shall pay the fee when the application for registration or reregistration is submitted for filing online using the secure application portal at *www.DEAdiversion.usdoj.gov*.

(b) Payment shall be made online by Automated Clearing House funds transfer, by credit card, or by any other means made available at the time of submission using the secure application portal at *www.DEAdiversion.usdoj.gov*.

6. Amend § 1309.32 by revising paragraphs (a) through (c) to read as follows:

§ 1309.32 Application forms; contents; signature.

(a) Any person who is required to be registered pursuant to § 1309.21 and is not so registered, shall apply on DEA Form 510 using the secure application portal at *www.DEAdiversion.usdoj.gov*.

(b) Any person who is registered pursuant to § 1309.21, shall apply for reregistration on DEA Form 510a using the secure application portal at *www.DEAdiversion.usdoj.gov*.

(c) DEA Forms 510 and 510a may be obtained online at *www.DEAdiversion.usdoj.gov*. DEA will send renewal notifications via email to registrants approximately calendar 60 days prior to their registration expiration date. Registrants are responsible for keeping their email address current in the secure application portal on DEA's website throughout the duration of their registration. Only applications submitted online through the secure application portal on DEA's website will be accepted for processing.

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7. Revise § 1309.33 to read as follows:

§ 1309.33 Filing of application; joint filings.

All applications for registration shall be submitted online at *www.DEAdiversion.usdoj.gov* for filing. The appropriate registration fee and any required attachments must accompany the application.

8. Amend § 1309.34 by revising paragraph (a) to read as follows:

§ 1309.34 Acceptance for filing; defective applications.

(a) Applications submitted for filing are dated upon receipt. If the application is found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not be accepted for filing.

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PART 1321—DEA MAILING ADDRESSES

9. The authority citation for part 1321 continues to read as follows:

Authority: 21 U.S.C. 871(b).

10. Amend § 1321.01 by revising the entries in the table under “DEA Registration Section” to read as follows:

§ 1321.01 DEA mailing addresses.

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Table of DEA Mailing Addresses

Code of Federal Regulations Section - Topic	DEA mailing address
* * * * *	
DEA Registration Section	
1301.03—Procedures information request (controlled substances registration). 1301.18(c)—Research project controlled substance increase request. 1301.51—Controlled substances registration modification request. 1301.52(b)—Controlled substances registration transfer request. 1301.52(c)—Controlled substances registration discontinuance of business activities notification. 1309.03—List I chemicals registration procedures information request. 1309.61—List I chemicals registration modification request.	Drug Enforcement Administration, Attn: Registration Section/DRR P.O. Box 2639, Springfield, VA 22152
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Anne Milgram
Administrator